SAUFLON CLARITI (SOMOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS WITH UV BLOCKER AND HANDLING TINT

510(K) SUMMARY AS REQUIRED BY SECTION 807.92(c)

1.- SUBMITTER INFORMATION:

Company Name: Sauflon Pharmaceuticals Ltd.

Address: 49 – 53 York Street
Twickenham
Middlesex
TW1 3LP

Phone: 020 8322 4200

Fax: 0845 051 8701

Contact Person: Dr Christopher Smejkal

DATE SUMMARY PREPARED: 24th January 2014

DEVICE NAME:

Trade Name: Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker and Handling tint

Common Name: Soft Contact Lens

Classification: CLASS II (21 CFR 886.5925) CODE –LPL,
SOFT (HYDROPHILIC) CONTACT LENS

Duration of Use:

Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact lens with UV Blocker and handling tint is a daily wear, frequent replacement lens for surface contact of the eye, and intended for daily removal and less than 24 hours contact duration.

2.- SUBSTANTIAL EQUIVALENCE:

The sponsor considers the Sauflon Clariti (somofilcon A) Soft (hydrophilic) with UV Blocker and handling tint to be substantially equivalent to the Sauflon Clariti (Somofilcon A) Soft (Hydrophilic) Lens for Daily Wear which has been approved pursuant to K130342, and Air Optix Aqua (Lotrafilcon B) Soft (Hydrophilic) Visibility

SAUFLON CLARITI (SOMOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS WITH UV BLOCKER AND HANDLING TINT
Tinted Contact Lens for Daily Wear which has been approved pursuant to K033919/K073459.

3.- DESCRIPTION of the DEVICE:

The Sauflon Clariti (somofilcon A) Soft (Silicone Hydrogel) Contact Lens with UV Blocker and handling tint is available as a single vision, toric and multifocal lens. The lens material (somofilcon A) is a hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with Alkyl bis methacrylate. When hydrated the lens consists of 44.0% somofilcon A and 56.0% water by weight of saline immersed in normal saline. A benzophenone UV absorbing monomer is used to block UV radiation. A D&C Green 6 tint is also included in the composition of the lens for ease of handling and visibility.

The average transmittance characteristics are less than 5% in the UVB range of 280 to 315nm and less than 50% in the UVA range of 316-380nm

The Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker and Handling Tint is spherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

- Chord Diameter: 13.0 to 18.0mm
- Centre Thickness: 0.03 to 0.70mm
- Base Curve: 7.5 to 9.5mm
- Powers: -30.00 DS to +30.00 DS
- Toric cylinder options: Between -0.75 and -9.75
- Toric Axis options: 10° to 180° (5° steps)
- Multifocal ADD:

  Add power of up to +4.00, labelled with indicative add strength to be read in conjunction with the fitting guide.

The physical/optical properties of the lenses are:

- Refractive Index: 1.4008
- %Transmittance @ 590nm: 98.30%
- %Transmittance @ 280-315nm: 0.71
- %Transmittance @ 316-380nm: 20.62
- Surface Character: Hydrophilic
- Water Content: 56%

SAUFLON CLARITI (SOMOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS WITH UV BLOCKER AND HANDLING TINT

- Oxygen Permeability (DK): 60×10^{-11} (cm^2/sec) (ml O2/ml x mmHg) at 35°C (Fatt Method for determination of oxygen permeability).
- Specific Gravity: 1.17

4.- INDICATIONS FOR USE

The **SAUFLON CLARITI** (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **SAUFLON CLARITI TORIC** (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.

The **SAUFLON CLARITI MULTIFOCAL** (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +4.00 Diopters or less.

The **SAUFLON CLARITI MULTIFOCAL TORIC** (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and that may require a reading addition of +4.00 Diopters or less.

The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion as recommended by the eye care professional.

Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact lens with UV blocker and handling tint helps protect against transmission of harmful UV radiation to the cornea and into the eye.

SAUFLON CLARITI (SOMOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS WITH UV BLOCKER AND HANDLING TINT
5.- PREDICATE DEVICES

The sponsor considers the SAUFLON CLARITI (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker and handling tint to be substantially equivalent to the Sauflon Clariti (Somofilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear which has been approved pursuant to K130342, and Air Optix Aqua (Lotrafilcon B) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear which has been approved pursuant to K033919/K073459.

The following table summarises the primary features for this comparison, illustrating the similarities and differences.

SAUFLON CLARITI (SOMOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS WITH UV BLOCKER AND HANDLING TINT

Table 6.1. Comparison of Physical / Optical Properties for the SAUFLON CLARITI (Somofilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker and Handling Tint versus Sauflon Clariti (Somofilcon A) Soft (Hydrophilic) and Air Optix Aqua (Lotrafilcon B) Soft (Hydrophilic) Visibility Tinted Contact Lenses for Daily Wear

	PREDICATE DEVICE - SAUFLON CLARITI WITH UV BLOCKER (K130342)	**PREDICATE DEVICE – AIR OPTIX** (K033919/K073459)	**SUBJECT DEVICE - SAUFLON CLARITI WITH UV BLOCKER AND HANDLING TINT**
LENS MATERIAL	Somofilcon A Silicone Hydrogel	Lotrafilcon B Silicone Hydrogel	Somofilcon A Silicone Hydrogel
INDICATIONS FOR USE	Daily wear monthly replacement	Daily wear monthly replacement	Daily wear monthly replacement
MANUFACTURING PROCESS	Cast Moulding	Cast Moulding	Cast Moulding
WATER CONTENT	56%	33%	56%
REFRACTIVE INDEX	1.40	1.42	1.40
LIGHT TRANSMITTANCE	≥96%	≥96%	≥96%
DK @35°C (EDGE CORRECTED)	60 (polarographic method)	110 (Coulometric method)	60 (polarographic method)
COLOUR	No Visibility Tint	Blue Visibility Tint	Blue Visibility Tint

SAUFLON CLARITI (SOMOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS WITH UV BLOCKER AND HANDLING TINT

TINT	No Visibility Tint	Copper phthalocyanine	D&C Green 6
UV BLOCKER	Benzophenone	None	Benzophenone
MODULUS (MPa)	0.55	0.92	0.55
TENSILE STRENGTH (MPa)	1.05	0.9	1.05
ELONGATION AT BREAK %	163	205	163
PACKAGING MATERIALS	Injected molded polypropylene blisters or Sabic PP PCGH19 covered by aluminium foil laminate and blister strips are packed into printed cartons	Injected molded polypropylene blisters covered by aluminium foil laminate and blister strips are packed into printed cartons	Injected molded polypropylene blisters or Sabic PP PCGH19 covered by aluminium foil laminate and blister strips are packed into printed cartons
PACKAGING SOLUTION	Borate buffered saline solution containing 0.005% poloxamer 407.	Phosphate buffered saline solution	Borate buffered saline solution containing 0.005% poloxamer 407.
PACKAGING METHOD	Hermetically sealed blister pack	Hermetically sealed blister pack	Hermetically sealed blister pack

SAUFLON CLARITI (SOMOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS WITH UV BLOCKER AND HANDLING TINT

6.- PHYSICOCHEMICAL STUDIES

The physical, optical and chemical properties of the lenses as assessed by various test methods show substantial equivalence with the predicate devices as illustrated in the preceding table. Studies were also conducted to verify that leachable substances were either low or below measurable levels to assuage any concerns for its intended use.

7.- TOXICOLOGY STUDIES

Toxicology testing demonstrates that Clariti (somofilcon A) Soft (Hydrophilic) with UV blocker and handling tint is non-toxic in all cytotoxicity, ocular irritation and acute systemic toxicity tests. This lens is therefore equivalent in terms of biocompatibility to the predicate devices specified.

8.- EVALUATION OF DYE LEACHABILITY

Dye leachability was evaluated and no dye was observed to leach from Sauflon Clariti (Somofilcon A) Soft (Hydrophilic) Contact Lenses with UV Blocker and handling tint after 14 days soaking in saline at 37°C.

9.- HUMAN CLINICAL STUDIES

A clinical study was conducted to evaluate the safety and efficacy of SAUFLON CLARITI (somofilcon A) Soft (hydrophilic) with UV Blocker and handling tint by comparison with Air Optix Aqua hydrophilic contact lenses (Ciba Vision Inc.). Subjects used OptiFree Replenish solution (Alcon Laboratories Inc.) for daily lens maintenance, care and storage. The results of this study showed the safety, acceptability and substantial equivalence of the Sauflon CLARITI (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker and handling tint to the predicate device for its intended use.

10.- CONCLUSIONS

Based on the above evaluations the SAUFLON CLARITI (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker and handling tint is substantially equivalent to the predicate, marketed lenses. Based on these evaluations the SAUFLON CLARITI (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker and handling tint has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2014

Sauflon Pharmaceuticals Ltd.
Dr. Christopher Smejkal
Head of Regulatory and Technical Affairs
49-53 York Street
Twickenham. Middlesex
TW1 3LP, United Kingdom

Re: K133740
Trade Name: Sauflon Clariti (somofilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker and Handling Tint
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: II
Product Code: LPL
Dated: January 24, 2014
Received: January 29, 2014

Dear Dr. Smejkal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133740

Device Name
Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint.

Indications for Use *(Describe)*

The SAUFLON CLARITI (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The SAUFLON CLARITI TORIC (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.

The SAUFLON CLARITI MULTIFOCAL (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +4.00 Diopters or less.

The SAUFLON CLARITI MULTIFOCAL TORIC (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker and handling tint is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and that may require a reading addition of +4.00 Diopters or less.
The lenses may be prescribed for daily wear for up to one month with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion as recommended by the eye care professional.

Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact lens with UV blocker and handling tint helps protect against transmission of harmful UV radiation to the cornea and into the eye. The lens has a tint added to make the lens more visible for handling.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Marc W. Robboy -S
2014.02.18 09:13:27 -05'00'

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